

Exhibit 15

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the Quarterly Period Ended March 31, 2001

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (D)
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER 1-9898

ORGANOGENESIS INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of
incorporation or organization)

04-2871690

(I.R.S. Employer
Identification number)

150 DAN ROAD, CANTON, MA

(Address of principal executive offices)

02021

(Zip Code)

Registrant's telephone number, including area code: (781) 575-0775

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes (X) No ()

The number of shares outstanding of registrant's Common Stock, par value \$.01 per share, at April 25, 2001 was 34,472,460 shares (excluding treasury shares).

ORGANOGENESIS INC.

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In this report, "Organogenesis" "we" "us" and "our" refer to Organogenesis Inc.

PART I - FINANCIAL INFORMATION
Item 1 - Financial Statements

ORGANOGENESIS INC.

Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2000	March 31, 2001
	-----	-----
ASSETS		(unaudited)
Current assets:		
Cash and cash equivalents	\$ 9,539	\$ 2,289
Investments	2,644	1,457
Inventory	1,377	1,349
Receivable from related party	501	1,544
Other current assets	758	742
Total current assets	14,819	7,381
Property and equipment -		
Less accumulated depreciation of \$13,600 and \$14,421	12,608	12,861
Other assets	445	420
Total Assets	\$ 27,872	\$ 20,662
	=====	=====
Liabilities		
Current liabilities:		
Accounts payable	\$ 2,378	\$ 2,395
Accrued expenses	3,582	3,451
Current portion of term loan	1,576	1,576
Deferred revenue	1,057	1,057
Total current liabilities	8,593	8,479
Deferred revenue	4,228	4,984
Long-term convertible debt	16,077	16,162
Term loan	2,758	2,364
Commitments (see notes)		
Stockholders' Deficit		
Common stock, par value \$.01; authorized 80,000,000 shares:		
Issued 34,489,459 and 34,406,043 shares as of		
December 31, 2000 and March 31, 2001, respectively	346	347
Additional paid-in capital	154,646	154,972
Accumulated deficit	(157,972)	(164,474)
Treasury stock at cost, 85,000 shares at December 31, 2000		
and 250,000 shares at March 31, 2001	(804)	(2,172)
Total stockholders' deficit	(3,784)	(11,327)
Total Liabilities and Stockholders' Deficit	\$ 27,872	\$ 20,662
	=====	=====

The accompanying notes are an integral part of
the consolidated financial statements.

ORGANOGENESIS INC.

Consolidated Statements of Operations
(Unaudited, in thousands, except share and per share data)

	For the Three Months Ended March 31,	
	2000	2001
	(Restated Note 2)	
REVENUES:		
Research, development and milestone support from related party	\$ 264	\$ 264
Product sales to related party	646	1,835
Research and development grants	184	412
Other revenues	67	-
Total Revenues	1,161	2,511
Costs and Expenses:		
Cost of product sales to related party	1,467	2,196
Research and development	4,042	4,656
General and administrative	1,782	1,739
Total Costs and Expenses	7,291	8,591
Loss from operations	(6,130)	(6,080)
Other income (expense):		
Interest income	187	98
Interest expense	(479)	(520)
Net loss before cumulative effect of change in accounting principle	(6,422)	(6,502)
Cumulative effect of adopting Staff Accounting Bulletin 101 ("SAB 101")	(6,342)	-
Net loss	\$ (12,764)	\$ (6,502)
Net loss per common share - basic and diluted before cumulative effect of change in accounting principle	\$ (0.21)	\$ (0.19)
Cumulative effect of adopting SAB 101	(0.20)	-
Net loss per common share - basic and diluted	\$ (0.41)	\$ (0.19)
Weighted average number of common shares outstanding - Basic and diluted	31,258,452	34,395,471

The accompanying notes are an integral part of
the consolidated financial statements.

ORGANOGENESIS INC.

Consolidated Statements of Cash Flows
(Unaudited, in thousands)

	For the Three months Ended March 31,	
	2000	2001
	(Restated Note 2)	
Cash flows from operating activities:		
Net loss	\$ (12,764)	\$ (6,502)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation	437	821
Amortization of warrants and deferred debt issuance costs relating to long-term convertible debt	119	110
Cumulative effect of adopting SAB 101	6,342	-
Changes in assets and liabilities:		
Inventory	(66)	28
Other current assets and receivable from related party	(193)	(1,027)
Accounts payable	(844)	17
Accrued expenses and other current liabilities	3,954	(131)
Advance from related party	5,000	-
Deferred revenue	(264)	756
Cash provided by (used in) operating activities	1,721	(5,928)
Cash flows from investing activities:		
Capital expenditures	(1,320)	(550)
Capital expenditures reimbursed from related party	-	(524)
Sales and maturities of investments	2,067	1,187
Cash provided by investing activities	747	113
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of term loan	(394)	(394)
Preferred stock redeemed in cash	(6,180)	-
Proceeds from sale of common stock - net	15,930	-
Proceeds from exercise of stock options	10,127	327
Purchase of treasury stock	-	(1,368)
Cash provided by (used in) financing activities	19,483	(1,435)
Increase (decrease) in cash and cash equivalents	21,951	(7,250)
Cash and cash equivalents, beginning of period	5,727	9,539
Cash and cash equivalents, end of period	\$ 27,678	\$ 2,289
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Interest paid in cash during the period	\$ 65	\$ 146

The accompanying notes are an integral part of
the consolidated financial statements.

ORGANOGENESIS INC.

Notes to Consolidated Financial Statements
(Unaudited)1. Basis of Presentation

The accompanying unaudited consolidated financial statements of Organogenesis Inc. have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the financial position, results of operations and changes in cash flows for the periods presented. The results of operations for the three months ended March 31, 2001 are not necessarily indicative of the results to be expected for the year ending December 31, 2001.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Form 10-K for the year ended December 31, 2000 as filed with the Securities and Exchange Commission.

Certain reclassifications have been made to the prior period financial statements to conform to the current presentation.

2. Revenue Recognition

We previously recognized up front non-refundable research and development support payments as revenue when received. During the year ended December 31, 2000, the Company changed its method of accounting for up front non-refundable research and development support payments to recognize such amounts over the term of the related collaboration with Novartis Pharma AG ("Novartis"). This change in accounting principle is in accordance with guidance provided in SEC Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB 101), which was issued in December 1999 and summarizes certain of the Staff's views in applying generally accepted accounting principles to revenue recognition in financial statements. We adopted SAB 101 in the fourth quarter of 2000, retroactive to January 1, 2000, and recorded the cumulative effect of a change in accounting principle related to all up front non-refundable research and development support payments recognized in prior periods of \$6,342,000. Of this amount, \$1,057,000 was recognized as revenue in 2000, \$264,000 was recognized as revenue during the first quarter of 2001 and the remaining \$5,021,000 will be recognized ratably through December 2005, in accordance with SAB 101's guidance.

Revenues from non-refundable milestone payments are recognized when proceeds are received and the related costs and effort are considered substantive. No milestone revenues from the receipt of milestone payments were recorded during the three months ended March 31, 2001.

Revenue from product sales are recognized upon shipment or, in certain cases, after fulfillment of firm purchase orders in accordance with a Manufacturing and Supply Agreement with Novartis and after risk of ownership passes to the buyer, collection is probable and we have no performance obligations. Product revenues which are performance based are deferred until performance is achieved. Revenues from product sales for the first quarter of 2001 totaled \$1,835,000. At March 31, 2001, we had \$48,000 of deferred performance based revenue.

Revenue for funding received from Novartis for reimbursement of manufacturing facility expenditures is recognized over the period that the completed manufacturing facility is used for production of Apligraf to be sold to Novartis. The funding will be used to support facility investment needed for the approval and sale of Apligraf in the European Union. During the first quarter of 2001, we received \$972,000 from Novartis for reimbursement of manufacturing facility costs of which \$524,000 was spent during the three months ended March 31, 2001 and \$448,000 was spent in prior periods.

Revenue from grants is recognized to the extent of allowable costs incurred. We have recorded revenue of \$412,000 for the three months ended March 31, 2001, of which \$309,000 relates to a grant under the Advanced Technology Program of the National Institute for Standards and Technology (refer to the "Grant Commitment" footnote) and \$103,000 relates to other research grants.

3. Net Loss Per Common Share

Net loss per common share (basic and diluted) is based on the weighted average number of common shares outstanding during each period. Potentially dilutive securities at March 31, 2001 include: stock options outstanding to purchase 3,654,266 common shares; warrants to purchase 900,000 common shares; and debt convertible into 1,694,968 common shares; however, such securities have not been included in the net loss per common share calculation because their effect would be antidilutive. Potentially dilutive securities at March 31, 2000 included: stock options outstanding to purchase 5,222,810 common shares; warrants to purchase 900,000 common shares; and debt convertible into 1,957,384 common shares; however, such securities have not been included in the net loss per common share calculation because their effect would be antidilutive.

4. Inventory

Inventory is stated at the lower of cost or market, cost being standard cost, which approximates the first-in, first-out method of accounting. Inventory, at net realizable value, consisted of the following (in thousands):

	December 31, 2000	March 31, 2001
	----	----
		(unaudited)
Raw materials	\$ 488	\$ 416
Work in process	889	933
	-----	-----
	\$1,377	\$1,349
	=====	=====

5. Related Party Transactions

In January 1996, we entered into a collaborative agreement with Novartis granting Novartis exclusive global marketing rights to Apligraf. Under the agreement, we have received equity investments, non-refundable research, development and milestone support payments, product payments and other payments. Product and other payments are included under the captions "Product sales to related party" and "Other revenues" in our financial statements.

In February 2001, we amended our collaborative agreement with Novartis, effective January 2, 2001. The amended agreement:

- o Grants Novartis the right to purchase an exclusive option to negotiate terms to license Organogenesis's product Vitrix(TM), soon to commence human pivotal trials, and also for a second living dermal replacement product currently in Organogenesis research;
- o Provides Organogenesis with significantly higher payments for units of Apligraf;
- o Grants Organogenesis the right for three years to sell, at its discretion, to Novartis up to \$20 million in equity;
- o Includes funding support from Novartis to upgrade Organogenesis's manufacturing facility and for the facility investment needed for approval and sale of Apligraf in the European Union;
- o Includes funding support for Apligraf clinical development activities (e.g., to further broaden its approved uses); and
- o Includes development funding support for each living dermal replacement product for which Novartis purchases an option to commence licensing negotiations.

We supply Novartis's global requirements for Apligraf and receive a product payment based on net product sales. Receivable from related party consists of amounts due on product sales to Novartis, funding of certain programs by Novartis and reimbursement of certain test costs related to the manufacturing of the product. Novartis is billed weekly for payments due on product sales and on an as incurred basis for other billings.

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2000	March 31, 2001
	----	-----
		(unaudited)
Compensation and employee benefits	\$1,869	\$1,742
Professional services	734	446
Accrued interest	368	632
Other	611	631
	-----	-----
	\$3,582	\$3,451
	=====	=====

7. Term Loan Agreement

In November of 1999, we entered into a \$5,000,000 term loan agreement with a commercial bank to finance the purchase of certain equipment, leasehold improvements and other items. Borrowings under the term loan are collateralized by a security interest in the items financed. The agreement provides for repayment of the principal amount of the loan in 12 equal quarterly installments commencing December 29, 2000, with final payment due on September 30, 2003. The loan bears interest at a fluctuating rate per annum that is equal to the prime rate in effect from time to time, or we may elect that all or any portion of any term loan be made as a LIBOR loan with an interest period of one month, two months, three months or six months with the interest rate being equal to LIBOR plus an applicable margin (175 to 225 basis points). We are required to comply with certain covenants relating to our outstanding term loans, involving limitations on future indebtedness, dividends and investments, and to maintain certain financial covenants pertaining to liquidity, capital base, and debt service coverage (or, alternatively, maintaining a minimum unencumbered cash balance). We borrowed approximately \$4,728,000 against this term loan to finance certain research, manufacturing and office equipment and leasehold improvements.

Effective December 29, 2000, we amended our covenants for the period through July 1, 2001, to include the effect of exercising a portion or all of the \$20,000,000 equity security put with Novartis in the financial covenants calculation. We anticipate raising additional funds that may be available through equity or debt financing, strategic alliances with corporate partners, capital lease arrangements, or other sources of financing in the future. However, if we fail to meet any of the financial covenants after April 30, 2001, we are required to exercise a portion or all of the equity security put with Novartis to maintain compliance. We had \$3,940,000 outstanding at March 31, 2001. The weighted average interest rate paid during this period was 8.42%. This borrowing is collateralized by a security interest in the fixed assets financed.

8. Grant Commitment

In November 1999, we received notice of a \$2,000,000 grant under the Advanced Technology Program of the National Institute for Standards and Technology ("NIST") to help support development of an effective liver assist device prototype, of which we have received \$1,050,000 and expect to receive the remaining amount over the period through December 2001. This grant requires that the United States federal government can access for its own purpose technology developed using the funding. A product developed based on the funding from the NIST grant must be manufactured substantially in the United States. In addition, we are subject to regular audit and reporting requirements. We have recorded revenue of \$309,000 for the three months ended March 31, 2001 relating to this research grant.

9. Common Stock Issuance

During the three months ended March 31, 2001, we issued 81,584 shares of common stock for the exercise of employee stock options, yielding proceeds of approximately \$327,000.

10. Treasury Stock:

In December 2000, the Board of Directors authorized a common stock repurchase program for up to 500,000 shares. Repurchases are allowed through open-market transactions that will provide us with shares for general corporate purposes. During the first quarter of 2001, we repurchased 165,000 shares of common stock for an aggregate purchase price of approximately \$1,367,000. The stock repurchase program may be discontinued at any time.

We had in treasury 85,000 shares of common stock at a cost of \$804,000 and 250,000 shares of common stock at a cost of \$2,172,000, at December 31, 2000 and March 31, 2001, respectively.

ORGANOGENESIS INC.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Form 10-Q contains forward-looking statements that involve risks and uncertainties. Forward-looking statements include information on:

- o Our business outlook and future financial performance;
- o Anticipated profitability, revenues, expenses and capital expenditures;
- o Anticipated research, development, clinical, regulatory and reimbursement progress;
- o Future funding and expectations as to any future events; and
- o Other statements that are not historical fact and are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties.

Although we believe that our plans, intentions and expectations reflected in or suggested by such forward-looking statements are reasonable, we can give no assurance that such plans, intentions or expectations will be achieved. When considering such forward-looking statements, you should keep in mind the risk factors and other cautionary statements in this Form 10-Q and in other publicly available filings with the US Securities and Exchange Commission ("SEC"), such as our Annual Report on Form 10-K for the year ended December 31, 2000. The risk and other factors noted throughout this Form 10-Q could cause our actual results to differ materially from the results contained in any forward-looking statements.

In Management's Discussion and Analysis ("MD&A"), we explain the general financial condition and results of operations for Organogenesis Inc. As you read this MD&A, referring to our consolidated financial statements contained in Item 1 of this Form 10-Q may be helpful. Results of operations may vary significantly from quarter to quarter depending on, among other factors, the progress of our research and development efforts, the receipt of research, development and milestone support payments, if any, from Novartis, product revenues, manufacturing costs, the timing of certain expenses and the establishment of additional collaborative agreements, if any.

Overview of Organogenesis Inc.

Organogenesis Inc. - a tissue engineering company - designs, develops and manufactures medical products containing living cells and/or natural connective tissue. We are the developer and manufacturer of the only mass-produced product containing living human cells to gain US Food and Drug Administration ("FDA") marketing approval. Our product development focus includes living tissue replacements, a cell-based organ assist device and other tissue-engineered products.

Our Lead Product, Apligraf(R)

Apligraf living skin substitute is FDA approved and marketed for use in the treatment of healing-resistant venous leg ulcers and diabetic foot ulcers. Novartis Pharma AG ("Novartis") has exclusive global Apligraf marketing rights. In August 2000, Apligraf qualified nationally for reimbursement when applied in a hospital outpatient setting. In February 2001, the Health Care Financing Administration classified Apligraf as a biologic for reimbursement purposes when applied in a doctor's office; this facilitates the process of gaining payment for Apligraf in that setting at the local level. In addition to being marketed in the United States, Apligraf is also available in select international markets. In April 2001, Novartis submitted the regulatory filing for marketing approval across the European Union.

Apligraf(R) is a registered trademark of Novartis.

A pivotal trial is underway to assess the ability of Apligraf to reduce scarring after skin cancer surgery. We expect to complete this trial and submit to the FDA for marketing approval within the next twelve months. As a skin substitute, we believe Apligraf has a number of additional potential uses, including pressure ulcers, burns, epidermolysis bullosa (a genetic skin disorder) and other chronic and acute wounds.

Our Pipeline

Our research and development pipeline includes a living dermal replacement product candidate, Vitrix. In March 2001, we applied to the FDA for permission to initiate a Vitrix human pivotal trial in deep diabetic foot ulcers. Our pipeline also includes a coronary vascular graft and a liver assist device, both currently in animal studies.

In March 2001, our Technology Ventures business unit established a collaboration with Royce(R) Medical Company to commercialize certain uses of our engineered collagen technology. In April 2001, the unit submitted to the FDA three 510(k) marketing applications for products composed of our engineered collagen.

Results of Operations

We are currently at a low volume production for Apligraf. Although revenues are ramping-up as evidenced by the quarterly growth of over 25% in each of the past two quarters, we expect production costs to exceed product sales for at least the next nine months due to the high costs associated with low volume production. We expect production volume to increase due to recent Medicare progress with coverage for Apligraf, FDA approval of Apligraf for use in diabetic foot ulcers and expanded Novartis sales and marketing support.

Revenues

Total revenues increased 116% to \$2,511,000 in the first quarter of fiscal 2001, from \$1,161,000 for the comparable quarter last year, due to: significantly higher payments received for units of Apligraf sold to Novartis under the amended collaborative agreement that became effective January 2, 2001; increased unit sales of Apligraf to Novartis; and increased funding received under our NIST research grant. We expect Apligraf commercial sales to continue to increase.

Costs and Expenses

Cost of product sales: Cost of product sales increased 50% to \$2,196,000 in the first quarter of fiscal 2001, from \$1,467,000 for the comparable quarter last year, due to increased unit sales of Apligraf to Novartis. Cost of product sales includes the direct costs to manufacture and package Apligraf and an allocation of our production related indirect costs. Cost of product sales continues to exceed product sales due to the high costs associated with low volume production. We expect production volume to increase and our margins to continue to improve during 2001.

Royce(R) is a registered trademark of Royce Medical Company

Research and development: Research and development expenses ("R&D") consist of costs associated with research, development, clinical, process development, facilities and engineering support excluding the allocation of our production related indirect costs. These expenses increased 15% to \$4,656,000 in the first quarter of fiscal 2001, from \$4,042,000 for the comparable quarter last year, due to: increased clinical outside service and consulting costs related to further broadening Apligraf uses; increased process development costs related to manufacturing improvement programs and increased product development costs related to our newly formed Technology Ventures business unit. We expect that R&D expenses will increase moderately during 2001.

General and administrative expenses: General and administrative expenses ("G&A") include the costs of our corporate, finance, information technology and human resource functions. These expenses decreased 2% to \$1,739,000 in the first quarter of fiscal 2001, from \$1,782,000 for the comparable quarter last year, due to lower occupancy and consulting costs. We expect that G&A expenses will decrease during 2001 as we expect to use less outside services.

Other income and expense: Interest income decreased primarily due to the decrease in funds available for investment. Interest expense increased 9% to \$520,000 in the first quarter of fiscal 2001, from \$479,000 for the comparable quarter last year, due to no interest capitalization during 2001.

Net Loss

As a result of the net effects described above, we incurred a net loss of \$6,502,000 or \$(0.19) per share (basic and diluted), for the three months ended March 31, 2001, compared to \$6,422,000, or \$(0.21) per share (basic and diluted), before the cumulative effect of change in accounting principle, for the three months ended March 31, 2000, and a net loss effected for the change in accounting principle of \$12,764,000 or \$(0.41) per share (basic and diluted), for the three months ended March 31, 2000.

Capital Resources and Liquidity

Funds Used in Operations

At March 31, 2001, we had cash, cash equivalents and investments in the aggregate amount of \$3,746,000, compared to \$12,183,000 at March 31, 2000. Cash equivalents consist of money market funds, which are highly liquid and have original maturities of less than three months. Investments consist of securities that have an A or A1 rating or better with a maximum maturity of two years. Cash used in operating activities was \$5,928,000 for the three months ended March 31, 2001, compared to cash provided by operating activities of \$1,721,000 for the same period in 2000. The three month period ended March 31, 2000, included \$5,000,000 cash received from Novartis in advance of achievement of a milestone related to the diabetic foot ulcer indication.

Capital Spending

Capital expenditures were \$1,074,000 (of which \$524,000 was reimbursed by Novartis) and \$1,320,000 during the three months ended March 31, 2001 and 2000, respectively, primarily related to the further build-out of existing facilities to support Apligraf manufacturing. We will continue to utilize funds during 2001 to expand our existing facility in the areas of Apligraf manufacturing, packaging and other process development improvement programs, including funds which we will receive from Novartis to upgrade our manufacturing facility and for the facility investment needed for approval and sale of Apligraf in the European Union.

Novartis Support

During the first quarter of 2001, Novartis provided funding support of \$972,000 for upgrades to our manufacturing facility and for the facility investment needed for approval and sale of Apligraf in the European Union. We have recorded the full amount of this funding as deferred revenue for the period ended March 31, 2001. Revenue will be recognized over the period that the completed manufacturing facility is used for production of Apligraf to be sold to Novartis. We have spent \$524,000 during the three months ended March 31, 2001 and the remaining \$448,000 was spent in prior periods.

Financing

From inception, we have financed our operations substantially through private and public placements of equity securities, as well as receipt of research support and contract revenues, interest income from investments, sale of products and receipt of royalties. During the three months ended March 31, 2001, financing activities used cash of \$1,435,000 primarily due to the purchase of treasury stock totaling \$1,368,000 and payment of a term loan for \$394,000, partially offset by cash received from the exercise of stock options for \$327,000. Financing activities provided cash of \$19,483,000 for the three months ended March 31, 2000 primarily from the sale of common stock that generated net proceeds of \$15,930,000 and the exercise of stock options that generated \$10,127,000, partially offset by the redemption of Series C redeemable convertible preferred stock in cash for \$6,180,000.

Liquidity

Based upon our current plans, we believe existing cash and cash equivalents at March 31, 2001, together with the proceeds of product and other revenues in 2001 and proceeds available from exercising a portion or all of a \$20,000,000 equity security put with Novartis, which is at our discretion, will be sufficient to finance operations through at least the first quarter of 2002. We expect to raise additional funds in 2001 through equity financing. However, this statement is forward-looking and changes may occur that would significantly decrease available cash before such time. Factors that may change our cash requirements include:

- o Sales volume forecasts not achieved;
- o Delays in obtaining regulatory approvals of products in different countries, if needed, and subsequent timing of product launches;
- o Delays in commercial acceptance and reimbursement when product launches occur;
- o Changes in the progress of research and development programs; and
- o Changes in the resources devoted to outside research collaborations or projects, self-funded projects, proprietary manufacturing methods and advanced technologies.

Any of these events could adversely impact our capital resources, requiring us to raise additional funds. Management believes that additional funds may be available through equity or debt financing, strategic alliances with corporate partners, capital lease arrangements, or other sources of financing in the future. There can be no assurances that these funds will be available when required on terms acceptable to us, if at all. If adequate funds are not available when needed, we would need to delay, scale back or eliminate certain research and development programs or license to third parties certain products or technologies that we would otherwise undertake ourselves, resulting in a potential adverse effect on our financial condition and results of operations.

Additional Cautionary Considerations

We are subject to risks common to entities in the biotechnology industry, including, but not limited to, the following uncertainties:

- o Continued operating losses and the time required to achieve profitability;
- o Market acceptance of our products and successful marketing and selling of Apligraf by Novartis;
- o Development by competitors of new technologies or products that are more effective than ours;
- o Dependence on our strategic relationships to market our products;
- o Compliance with FDA regulations and similar foreign regulatory bodies;
- o Protection of proprietary technology through patents and risks of infringement claims by third parties;
- o Manufacture and sale of products in sufficient volume to realize a satisfactory margin;
- o Continued availability of raw material for products;
- o Product quality issues which could lead to product recalls;
- o Dependence on and retention of key personnel;
- o Availability of sufficient product liability insurance;
- o Adequate third-party reimbursement for products;
- o Stock price volatility and fluctuation;
- o Availability of additional capital on acceptable terms, if at all;
- o Affect of anti-takeover measures on the value of our stock;
- o Affect of outstanding options, warrants and convertible debt on the value of our stock; and
- o Risk of failure of clinical trials for future indications of Apligraf and for Vitrix and other products.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The exposure of market risk associated with risk-sensitive instruments is not material, as our sales are transacted primarily in United States dollars, we invest primarily in money market funds and we have not entered into hedging transactions.

ORGANOGENESIS INC.

PART II - OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

None

(b) Reports on Form 8-K filed during the quarter ended March 31, 2001.

A current report on Form 8-K dated March 8, 2001, as amended April 24, 2001, was filed by the Registrant reporting the following:

- o An announcement that the federal Health Care Financing Administration, which administers Medicare, has classified Apligraf as a biologic for reimbursement purposes when applied in a doctor's office.
- o An announcement of the signing of an amendment, effective January 2, 2001, to the Registrant's 1996 agreement with Novartis AG.
- o Other matters discussed on a conference call dated February 27, 2001.

ORGANOGENESIS INC.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Organogenesis Inc.
(Registrant)

Date: April 26, 2001

/S/ Philip M. Laughlin

Philip M. Laughlin, President
and Chief Executive Officer
(Principal Executive Officer)

Date: April 26, 2001

/S/ John J. Arcari

John J. Arcari, Vice President, Finance and
Administration, Chief Financial Officer
(Principal Financial and Accounting Officer)